Cancer Clinical Trials Advisory Council
Meeting Minutes
September 28, 2011

Council members present in person: **Jack Hensold, M.D.**, Bozeman Deaconess Cancer Center; **Brendan Steele**, Cancer Patient; **Paul Burns**, Cancer Patient; **Cory Hartman**, New West Health Services; **Ron Dewsnup**, Allegiance Benefit Plan Management; **Jo Duszkiewicz**, Billings Clinic; **Kristin Page Nei**, American Cancer Society Cancer Action Network; **Diane Ruff**, Associated Employers Group Benefit Plan & Trust; **Grant Harrer**, M.D., Benefis Health Systems; **Robert Geller, M.D.**, Billings Clinic; **Russ Hill**, DOA-Health Care and Benefits Administration; **Sharon DeJongh**, Bozeman Deaconess Cancer Center; **Ben Marchello**, M.D., Frontier Cancer Center and Montana Cancer Consortium
Council members present on the phone: **Monica Berner**, BCBS of MT; **Cori Cook**, EBMS; **Marien Diaz**, Symetra Life Insurance Company; **Michael Foster**, Catholic Hospitals

Council members Absent: **Paul Bogumill**, Mountain West Benefits

Insurance Commissioner Monica Lindeen called the meeting to order at 2:00pm and a quorum was established.

Greetings and summary of the council's charge from Commissioner Lindeen

Commissioner Lindeen thanked Rep. Kathleen Williams for successfully carrying the bill that authorized the study. She noted that bill charged her with carrying out some aspects of the study directly and asked her to seek advice from this advisory council on other issues. She stated her belief that the study would be a great benefit to cancer patients in Montana. She offered a special thanks to the cancer survivors for their participation.

Commissioner Lindeen noted that numerous social and political changes had occurred since the effort four years ago failed to produce an agreement. She encouraged the group to see these changes as a reason to believe the current effort can be more effective and successful. The passage of federal reform includes a provision requiring coverage of routine cancer care during clinical trials. The National Association of Insurance Commissioners (NAIC) is charged with helping the US Department of Health and Human Services propose regulations for many parts of the law and Commissioner Lindeen noted that she serves in leadership on the committee tasked with considering coverage for routine care of clinical cancer trials. She hopes the work of the Advisory Council will help inform her and the federal government as new regulations are developed.

Commissioner Lindeen further noted that advances in scientific and economic knowledge, the increased engagement of the public in health care, and the new professional interest in paying for and delivering health care in patient-centered ways should all help us move toward agreement.

Council election of presiding officer

CSI staff went over the duties of the chair:

- Determine meeting dates/approve meeting agendas/facilitate meetings
- Invite participation of all members; ensure that all are heard
- Determine how to move the Council to accomplish the goals
- Oversee assignments to staff and other Council members
- Call for votes of the council when needed
- Ensure the records of the committee are complete, that they represent the work of the Council , and that open meetings laws are followed

Kristin Page Nei was the only member who volunteered to be the chair. Several members spoke to her credibility and experience, and she was elected unanimously.

Administrative matters

Members were reminded that they were eligible to receive a $50 stipend for their work on the council and reimbursement for their travel expenses. They were also reminded that the only decisions that the council will make are recommendations to the Commissioner for her to present to the interim legislative committee.

Review of draft study plan – CSI

The Council reviewed each section of the draft study plan and suggested some specific minor changes. Staff was directed to make those changes and the plan was approved.

An insurance member noted the importance of understanding the difference between self-insured health plans and fully-insured health policies. He explained that the state has full jurisdiction over fully-insured health plans, and that self-insured policies are governed by federal law under ERISA. Before PPACA, there were very few mandates for self-funded plans and state mandates govern only fully-insured plans. PPACA now has mandates for ERISA plans including coverage of routine care during clinical trials. The stop loss plans provide a financial cover for expenses that exceed a defined level. The amount under that level would be covered by the employer. This study is dealing with not only the fully-insured plans that the state governs but also the self-funded plans that are ERISA based.

A conversation ensued about why clinical trials have become such an issue here in Montana, why there have been such problems with ERISA plans, what is involved in certain phase trials, why certain phases were not covered, and whether trials overlap various phases.

Members of the previous effort described the 2007 process. If the mandate bill had passed in 2005 or 2011, we would still have problems with ERISA plans. Insurance members stated that there has been a lot of movement among the self funded plans since 2009 and that although they have made the changes on their fully-insured side, the employers on their self-funded side pick and choose whether or not they would cover routine care during trials.

Provider members emphasized that the experimental parts of the treatments are not charged and that what needs to be covered are the costs of routine care for a patient undergoing clinical trials. Routine care under trials does not cost anymore than cancer treatment without a trial (which is expensive). The only reason routine care would cost more for a patient on a trial is if they live longer.

Insurance members agreed that there needs to be more transparency about what is and isn't covered by sponsoring organizations.

Panel of patients, insurance representatives, and providers describing their experiences with clinical trials

Brendan Steele described his experience with a very aggressive trial that including a treatment that was considered to be outside of routine care. He believed his self-funded insurance plan thought the extra treatment had the potential of interfering with the routine treatment and thus denied coverage of all treatments. Because he was given less than a year to live, he went ahead with the trial under coverage from a government-provided second insurance. Brendan was eventually told that his first insurance would cover routine care on the condition that if anything else came up it wouldn't be covered.

Paul Burns also described his experience with cancer and the same insurance since they both work for the city of Bozeman and have a self-funded plan. When he told his insurance company that his doctor determined him to be a perfect candidate for a clinical trial that would extend his life, he felt he was up against a stone wall. He said the insurance commissioner's office doesn't get more complaints because so often when people get in that position they don't know what to do next. He elaborated on all the actions he took, including calling the members of the board of the insurance company, all while with cancer, until the trial was approved.

Jack Hensold, M.D. spoke from the standpoint as a provider. When he assumes the care of a patient he has a contract to provide the best care possible for the patient. It is critically important that the patient has the trust in the provider that they will provide the best care. He described oncology as a knowledge-based specialty. Oncologists must understand the basis of treatments and the possibilities of on-going new treatments. Oncologists are taught how to critically review clinical trials, how to design clinical trials, and how to enroll patients in clinical trials. Clinical trials are really the knowledge basis of the specialty. The problem is a bigger issue in Montana than it is in other places. The only way we improve care for cancer patients is clinical trials, 3% of cancer patients nationwide go on clinical trials. Denying access to clinical trials is denying them access to best care. It is a waste of time and money not to use clinical trials. There are no additional costs to the system when putting patients on clinical trials. He noted that more denials occur among the association plans.

Jo Duszkiewicz of Billings Clinic spoke about clinical research and getting it into clinical practice. The American College of Surgeons believes clinical trials are important to the care of patients. Up until now cancer centers have been required to have 2% of their patients on clinical trials to receive certification from the National Cancer Institute. In 2012, to be an accredited organization, a center must have 4% of its patients on clinical trials. Billings Clinic is putting about 10% of patients on clinical trials in all four phases. It is part of their mission statement. Since January of 2010, they have had about 30 denials for

non-coverage. She notes an explosion of changes in all plans in the past few years on clinical trials. They have had denials from Medicare Advantage plans, even though Medicare covers. She suggested we look closer at our Montana clinics to see why there are denials. At Billings Clinic, 69% of denials were because they weren't covered in the policy. Some self pay patients have gone onto the Billings Clinic assistance plan to participate in clinical trials. They are getting approval from some companies for all three phases. They were not tracking until 3 or 4 years ago as part of the NCI.

Ben Marchello, M.D. of the Frontier Cancer Center stepped in for Amanda Dinsdale who was invited to speak on behalf of the Montana Cancer Consortium. Dr. Marchello reported that Ms. Dinsdale's survey of cancer centers revealed that Billings Clinic was the only clinic that kept records on coverage denials related to cancer trials.

[The Council wondered whether we should consider recommending that providers and insurers keep records]

Ron Dewsnup of Allegiance added to his earlier comments from a payer perspective. He served on the definitions subcommittee in 2007 and believed they were very close to getting agreement. He mentioned that he empathizes with the concerns of patients and providers but still has contracts to administer. Following changes in the last 3-4 years, Allegiance recommends its self-funded clients reference National Comprehensive Cancer Network (NCCN) guidelines among other guidelines for their covered services. The compounding of costs over the past years has been very frightening. Allegiance wants to make the process easier for the provider and patient while meeting financial and administration obligations and still administering a plan effectively. Contracts are written to prevent abuses that have happened in the past. "Routine care" and "standard of care" have two different definitions. Some trials require patients to go outside of the state.

Cory Hartman of New West Health Services provided another payer perspective. NWHS has made progress with respect to coverage policy for trials in the last several years, including a review of trials that the Billings Clinic was planning to offer to their patients in advance. Once the trial has been approved, no further review is needed for each additional request for participation. NWHS currently has a list of 20 trials which can be approved without a detailed medical review, as they have been previously approved and generally as they are phase 3 and deemed appropriate for coverage (except, of course, for any services supplied by the manufacturer).

From 2003-2011, NWHS has received requests for 85 clinical trials. Of these, 61 were approved, meaning either participation in the trial was approved, or reimbursement for the standard of care costs, were approved for those participating in trials. 13 of these were for self-funded plan members.

During this same timeframe NWHS had 6 requests for trial participation withdrawn by the member or provider as the patient did not meet criteria. NWHS has denied 24 requests for trial participation (8 of which were for self-funded plans), most commonly for the trial being in phase 1 or early phase 2. NWHS cannot ethically pay for care that may result in more harm than good for these early phase experimental trials as we are simply fiduciaries of our member's premiums.

Given that NWHS had less than 1% of membership request clinical trials in this reporting period of 8 years, and of those, 72% were approved, this does not seem to be a problem from New West's perspective for our fully-insured business.

Ms. Hartman suggested oncologists provide protocols and associated costs for typical trials in all phases to insurers on this Council that would help establish some common ground for conversation on definitions. She also suggested we might consider pursuing case rates like we do for transplants so that complications are covered.

She reported on comments from New West's current and previous medical directors on the failed agreement in 2007. Her written comments are attached.

Public Comments:

Becky Franks works with the Bozeman Deaconess Cancer support group. They work to empower people to ask questions and take actions that would improve their quality of life. Their program "Open to Options" helps patients access clinical trials. She urged the council to consider things from a patient perspective: how much energy it takes to fight cancer and their insurance companies. It is a huge problem; people get tired and can't fight anymore; they don't have the energy once they hear "no," they give up because they are sick.

Deanna Harrer works at Benefis Health System doing clinical research. Many patients need and want treatment right away. Dealing with insurance delays treatment. Insurance companies risk ratio has to work for them but even if patients weren't on a clinical trial they would still have to cover routine care. She noted that there are two kinds of clinical trials, those sponsored by the NCI and those sponsored by a drug company. Payments related to NCI –sponsored trials are specified up-front and cannot be negotiated. Drugs companies may be able to negotiate some additional payment. The difference needs to be made clear to insurance companies.

Representative Kathleen Williams said her bill started out as a mandate, but she rewrote it as a study bill with a few teeth. She thanked CSI for their efforts to date in the selection of an excellent Council and for providing compensation even though no money was appropriated. She wanted the council to consider that Brendan and Paul have the same insurer and had an inequitable result. She believes much has changed since the failed effort in 2007. 14 more states have legislation or agreements; clinical trials producing better results; more trials are being required for accreditation with NCI; and the promise of more on-line transparency will improve prospects for more agreement. She noted that the work plan did not contain any recommended study on transparency as identified in Section 3 of HB 615. She asked if that was intentional.

Council Discussion:

The Council continued with discussion on the causes for denials of routine care coverage in clinical trials.

Provider members discussed new research indicating that trails do not add to the costs of care. They pointed about that with only 3% of cancer patients in trials, this should not be as big a problem as it

seems. The denial process delays treatment critical to the successful outcomes for the patients. **They wondered if more education of insurers and employers was needed.**

Insurance members discussed evidence-based care as the standard, and the difficulty knowing what is and is not routine care especially without seeing the trial protocol. They pointed out that the key challenges that stalled the last clinical trials process was the issue of who will pay for complications and the administration of the clinical trial. They commented that to self-funded plans a concern is the stop loss coverage, and what that carrier may do if routine care during trials is now covered.

An employer member suggested that self-funded plans simply collected dollars to put them in the bucket to pay for all costs. Their stop loss threshold is high. For example it is often at $450,000. The self-funded organization's goal is to support positive employer and employee relationships. The word "trial" sounds experimental and isn't something they believe they can easily insure.

The chair reminded the Council that all of the Montanans that testified in 2007 were members of self-funded plans.

The following suggestions were made:

1. **Education of payors about clinical trials being the standard of care for most cancer treatments. This should include providing data that shows that the overwhelming majority of patients who choose clinical trials have not already gone through the standard of care treatment.**
2. **Education of providers about how to best to submit trial protocols and requests for coverage of routine care.**
3. **Education of Council about the difference between fully-insured and self-insured plans and the specific challenges each faces as related to payment of routine care during cancer clinical trials, as the concerns are not the same.**
4. **Education of the Council on the limitations of the concept of "Evidence-Based Care" for oncology where clinical trials are the "Standard of Care."**
5. **Dr. Hensold will send out research on the cost of care during cancer clinical trials to the Council and invite discussion among the group.**
6. **The Council should discuss how the patient/provider can increase their chance of success in getting the insurance providers to accept clinical trial coverage requests.**
7. **The Council should continue meeting in person for the near future, in order to further develop a relational basis for our work, and that we consider continuing to meet in Bozeman**

Meeting adjourned at 5:32pm

Bolded items highlight decisions or recommendations to be considered in the future